REMARKS

I. Claims

Claims 19-34, 36-39 and 40-44 are currently before the Office. Applicant acknowledges that the Office allowed claims 37-39. Claims 19-34 and 36 currently stand rejected by the Office. New claims 40-44 are added by this Amendment. Support for new claims 40-44 is found, for example, at paragraphs **[05]**, **[028]**, **[030]**, **[035]**, and **[054]** of the application. In particular, the "concentration of calcium from the TCP solution that is at least about 0.15 mg/mL" of claim 43 was arrived at by using a RDA of 400 mg, a 10% RDA per serving, a serving size of 9 fluid ounces (1 fluid ounce corresponds to about 29.5735 mL). Similarly, the "concentration of calcium from the TCP solution that is at least about 0.63 mg/mL" of claim 44 was arrived at by using a RDA of 1,500 mg, a 10% RDA per serving, and a serving size of 8 fluid ounces. As such, Applicant submits that no new subject matter was introduced by new claims 40-44.

II. Section 112

Claim 19 stands rejected pursuant to 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Office alleges that claim 19 is indefinite because the phrase "10-50% of the RDA of calcium per serving" in view of the fact that the recommended calcium intake per day varies with age.

Applicant acknowledges that the use of "10-50% of the RDA of calcium per serving", in view of the application, introduces variability into the claim, in part, because of the fact that the recommended calcium intake varies by age as noted by the Office. This fact is discussed in the present application at paragraph **[05]**. Applicant further notes that the exact volume of beverage that constitutes also varies, which is noted in the application at paragraph **[028]**. Although the exact concentration of calcium in a particular beverage produced according to the method of claim 19 may vary depending upon the particular class of consumer for which the beverage is designed and upon the

serving size of the particular beverage, this does not render the claim invalid as indefinite under §112, second paragraph for the reasons set forth below.

The Federal Circuit has stated that the purpose of the § 112 definiteness requirement is that it "assures that claims in a patent are sufficiently precise to permit a potential competitor to determine whether or not he is infringing." *Amgen, Inc. v. Hoechst Marion Rousel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003)(quoting *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993)). Further, "[t]he requirement . . . is met when a person experienced in the field of the invention would understand the scope of the subject matter that is patented when the claim is read in conjunction with the rest of the specification." *S3, Inc. v. Nvidia Corp.*, 259 F.3d 1364, 1367 (Fed. Cir. 2001). Applicant submits that one of skill in the art will know the particular class of consumer for which a beverage is designed. For example, many beverages marketed to the general public are typically directed to people of 19 to 51 years of age and a formulated accordingly. Additionally, Applicant submits that one of skill in the art will know what the recommended serving size of a particular beverage is or will be. For example, the typical serving sizes for juices and fortified waters are 4 and 8 ounces, respectively. See application at paragraph **[028]**. Thus, a person of skill in the art of preparing a calcium-supplemented fluid composition will know (1) the recommended daily amount of calcium intake of the fluid compositions intended consumers and (2) the serving size for the fluid composition and will be able to determine (3) whether he/she is dissolving tricalcium phosphate (TCP) in an acidulent solution to make a TCP solution with a pH of about 2 to about 3.5 and (4) whether he/she is combining the TCP solution with a sufficient amount of a transparent, ingestive liquid so that the calcium-supplemented fluid composition has about 10% to about 50% of the RDA of calcium per serving from the TCP solution. Therefore, claim 19, in view of the specification, is sufficiently precise to permit a potential competitor to determine whether he/she is infringing.

Based on the above, Applicant submits that the phrase "10-50% of the RDA of calcium per serving" is not indefinite and the claim 19 satisfies 35 U.S.C. § 112, second paragraph.

III. Section 103

Shigeru et al. is alleged by the Office to disclose a process of making a calcium supplemented fluid composition by dissolving tricalcium phosphate (TCP) in citric acid and the calcium concentration in the composition was 25 mmol/liter. As a result, the Office alleged that method of making a calcium-supplemented fluid composition set forth in claims 19-34 and 36 would have been obvious.

The Applicant respectfully disagrees with the Office concerning the disclosure set forth by Shigeru et al. and submits the Office has failed to set forth a *prima facie* case of obviousness. Specifically, section 2143 of the MPEP sets forth the three basic criteria to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success for the proposed modification or combination. Third, the prior art reference(s) must teach or suggest all the claim limitations. Further, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). In the present situation, the Office's asserted rejection of the claims as obvious over Shigeru et al. **does not satisfy any of the three necessary criteria**. First and foremost, as is set forth below **Shigeru et al. does not teach or suggest each and every claim limitation.** As such, it cannot be reasonably said that there is some motivation disclosed by Shigeru et al. or in the knowledge generally available to one of ordinary skill in the art to modify the Shigeru et al. Likewise, there cannot be a reasonable expectation of success.

Shigeru et al. disclose forming an aqueous calcium solution composition by dissolving a calcium phosphate constituent in an aqueous solution of an organic carboxylic acid constituent (e.g., a citric acid solution) and then adding the aqueous calcium solution to a soft drink. Shigeru et al., page 4, third paragraph to page 5, line 1.

Shigeru et al. disclose that the calcium phosphate constituent comprises at least one of the following:

> (a) a mixture of tricalcium α-phosphate and tetracalcium phosphate, wherein the mixture is obtained by dehydrating tribasic calcium phosphate at a temperature of at least 1,200 °C;
>
> (b) a water-soluble calcium compound such as calcium hydroxide or calcium carbonate; or
>
> (c) a reaction product of a mixture of a water-soluble calcium compound (e.g., CaOH and/or $CaCO_3$) and at least one of phosphoric acid, monobasic calcium phosphate, or dibasic calcium phosphate, wherein the mixture has a calcium to phosphoric acid radical mole ration of 1.5:1 to 2.0:1, and wherein the reaction product is the result of heating the mixture at a temperature of at least 1,200 °C.

In view of the foregoing disclosure by Shigeru et al., it is understandable why the Office considered the group (a) calcium phosphate constituent of a mixture of tricalcium α-phosphate and tetracalcium to render claim 19 obvious. **But tricalcium α-phosphate (α-tricalcium phosphate, α-$Ca_3(PO_4)_2$) is not the same as the tricalcium phosphate of the present invention**, which is hydroxyapatite or hydroxylapatite having the chemical formula ($Ca_{10}(OH)_2(PO_4)_6$) and was referred to by Shigeru et al. as tribasic calcium phosphate. See paragraph of **[033]** of the application; the attached table of Calcium Phosphates in the $CaO–P_2O_5–H_2O$ System; and Shigeru et al. at page 5, fourth paragraph. Unfortunately, the current rejection seems to based on confusion resulting from the industry's commercial use of the term "tricalcium phosphate" to refer to hydroxylapatite despite it being distinct from α-and β- tricalcium phosphate.

Importantly, it cannot be said that Shigeru et al. disclose, teach, or suggest using the Applicant's TCP (hydroxlyapatite or tribasic calcium phosphate as Shigeru et al.

describe it) because Shigeru et al. disclose that the Applicant's TCP must be heated to obtain a mixture of tricalcium α-phosphate and tetracalcium phosphate for dissolution in an carboxylic acid solution. Thus, Shigeru et al. impliedly disclose that using hydroxylapatite would **not** be operable. Otherwise, they would have simply used hydroxylapatite instead of performing the time consuming and costly step of heating the hydroxylapatite to at least at least 1,200 °C in order to transform the hydroxylapatite into two different compounds (i.e., tricalcium α-phosphate and tetracalcium phosphate). Further, in view of this it cannot be fairly said that there would have been a reasonable expectation of success in using hydroxylapatite as set forth in claim 19. To hold to the contrary would be improperly using hindsight or the Applicant's own disclosure as the basis of the rejection.

In view of the foregoing, independent claims 19, 36, and 43 are nonobvious and patentable over Shigeru et al. Likewise, claims 20-34 and 40-42, which depend directly or indirectly from claim 19, are nonobvious and patentable for the same reasons as claim 19 and 43 and in view of the additional requirements recited therein. Accordingly, the withdrawal of the rejections of claims 19-34 and 36 under 35 U.S.C. § 103(a) is respectfully requested. Applicant submits that the foregoing argument is equally applicable to rejected independent claim 36 and therefore the obviousness rejection should also be withdrawn. Still further, Applicant submits the foregoing argument is equally applicable to new independent claim 43 and claim 44, which depends therefrom.

IV. Conclusion

In view of the foregoing, Applicant respectfully submits that the present application is in condition for allowance and therefore requests that the Office issue a Notice of Allowance.

It is not believed that extensions of time or other fees are required. In particular, it is believed that no additional fees are necessary for the new claims because of the fees already paid with respect to cancelled claims. Nevertheless, in the event that additional extensions of time or other fees are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned for under 37 C.F.R. §1.136(a), and any fees required therefore or otherwise are hereby authorized to be charged to our Deposit Account 20-0823.

Respectfully submitted,

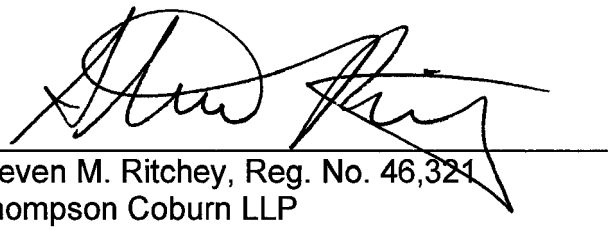

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Table 8. Calcium Phosphates in the $CaO-P_2O_5-H_2O$ System

Compound	CAS Registry Number	Formula	*Chemical Abstracts* or
calcium hydrogen phosphate	[*7757-93-9*]	$CaHPO_4$	dicalcium phosphate; mon
calcium hydrogen phosphate hemihydrate	[*78436-06-3*]	$CaHPO_4 \cdot 0.5H_2O$	metabrushite [*78436-06-3*]
calcium hydrogen phosphate dihydrate	[*7789-77-7*]	$CaHPO_4 \cdot 2H_2O$	brushite [*14567-92-1*]
α-tricalcium phosphate	[*7758-87-4*]	α-$Ca_3(PO_4)_2$	
β-tricalcium phosphate	[*7758-87-4*]	β-$Ca_3(PO_4)_2$	
octacalcium phosphate	[*14096-86-7*]	$Ca_8H_2(PO_4)_6 \cdot 5H_2O$	
hydroxyapatite	[*1306-06-5*]	$Ca_{10}(PO_4)_6(OH)_2$	
fluorapatite	[*1306-05-4*]	$Ca_{10}(PO_4)_6F_2$	
phosphoric acid			
calcium salt (2:1)	[*7758-23-8*]	$Ca(H_2PO_4)_2$	monocalcium phosphate (M
calcium salt hydrate (2:1:1)	[*10031-30-8*]	$Ca(H_2PO_4)_2 \cdot H_2O$	monocalcium phosphate m
calcium salt hydrate (2:1:2)	[*5221-07-5*]	$Ca(H_2PO_4)_2 \cdot 2H_2O$	monocalcium phosphate di